



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

June 25, 2002

**VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 02-52

Mr. Jeffery Noddle, President
SuperValu, Inc.
11840 Valley View Road
Eden Prairie, Minnesota 55344

WARNING LETTER

Dear Mr. Noddle:

On June 11 2002, Investigators Jonathan T. Little and Heika R. Bounds conducted an inspection of SuperValu International Division, 495 East 19th Street, Tacoma, Washington. The inspection was conducted to determine your firm's compliance with FDA's seafood processing regulations (21 Code of Federal Regulations (CFR) 123). The seafood processing regulations, which became effective on December 18, 1997, require that you have and implement written verification procedures to verify that your foreign suppliers have implemented a preventive system of food safety controls known as Hazard Analysis Critical Control Point (HACCP) in accordance with U.S. requirements.

The product covered during this inspection was canned tuna imported from [REDACTED]. At the conclusion of that inspection a list of violations (Form FDA 483) was presented to Mr. Charles K. Witzleben, President. These HACCP violation causes your imported products to be adulterated within the meaning of 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. Specifically,

In order to comply with 21 CFR 123.12(a)(2) and (2)(i), you must have written verification procedures which include product specifications that are designed to ensure that the fish and fishery products you import are not injurious to health. However, your firm has neither verification procedures nor product specifications for canned tuna from Thailand.

The above HACCP violations are not meant to be an all-inclusive list of deficiencies at your firm. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA. You should take prompt action to correct all HACCP

Mr. Jeffery Noddle, President
SuperValu Inc., Eden Prairie, Minnesota 55344
Re: Warning Letter SEA 02-52

2

violations. Failure to promptly correct these violations may result in regulatory action without further notice such as seizure and/or injunction. Furthermore, your firm and the foreign processor may be placed on import alert and future shipments of the product may be subject to detention without physical exam.

You should notify this office in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Your reply to these concerns should be addressed to Thomas S. Piekarski, Compliance Officer, at the address given above.

Sincerely,

A handwritten signature in black ink, appearing to read 'Charles M. Breen', with a long horizontal flourish extending to the right.

Charles M. Breen
District Director

Cc:

Mr. Charles K. Witzleben, President
SuperValu International Division
495 East 19th Street
Tacoma, Washington 98421

WSDA with disclosure letter